Section 5

Summary of Substantial Equivalence

Summary of Modifications

As shown previously in this submission, the Hemashield Platinum grafts are different from the Hemashield Gold grafts only in the label claim for permeability.

Substantial Equivalence

The modified vascular grafts have the following similarities to those which previously received 510(k) concurrence:

- Identical indications for use
- Identical labeling
- Identical manufacturing process flow
- Identical operating principle
- Incorporate identical materials
- Have the identical shelf-life (5 years)
- Are packaged and sterilized using identical packaging materials and processes

In summary, the Hemashield Platinum vascular grafts described in this submission are equivalent to the predicate device.

Continued on next page

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 9 2002

Ms. Jennifer Bolton, RAC
Senior Regulatory Affairs Specialist
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537

Re: K021213
Trade Name: Modification to Hemashield Platinum Woven/Microvel Double Velour
Regulation Number: 21 CFR 870.3460
Regulation Name: Vascular graft prosthesis of 6 millimeters and greater diameter.
Regulatory Class: Class II (two)
Product Code: MAL
Dated: April 16, 2002
Received: April 17, 2002

Dear Ms. Bolton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known)	Unknown
Device Name:	Hemashield Platinum Woven Double Velour Vascular Grafts Hemashield Platinum Microvel Double Velour Vascular Grafts
Indications for Use	The Hemashield Platinum vascular grafts are indicated for use in the replacement or repair of arteries affected with aneurysmal or occlusive disease. The prosthesis is also recommended for use in patients requiring systemic heparinization prior to, or during, surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K021213